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January 16, 2007

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Conf. No.: 4816
Art Unit: 1637
Examiner: Y.J. Kim

Re: U.S. Patent Application No. 09/394,745 filed September 15, 1999
Inventors: Dane K. FISHER *et al.*
Title: Nucleic Acid Molecules and Other Molecules Associated with Plants
Atty. Dkt: 16517.280

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appeal Brief under 37 C.F.R. § 41.37; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Authorization is hereby given to charge $500.00 for filing an Appeal Brief to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.280. A duplicate copy of this letter is enclosed.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.280. A duplicate copy of this letter is attached.

Respectfully submitted,

Enclosures

Thomas E. Holsten (Reg. No. 46,098)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	Confirmation No.: 4816
Dane K. FISHER *et al.*	Art Unit: 1637
Application Serial No.: 09/394,745	Examiner: Young J. Kim
Filed: September 15, 1999	Attorney Docket No.: 16517.280

Title: Nucleic Acid Molecules and Other Molecules Associated with Plants

Appeal Brief under 37 C.F.R. § 41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the Final Rejection of claims in the above-captioned patent application. A Notice of Appeal was filed on November 16, 2006. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

This application was previously appealed to the Board of Patent Appeals and Interferences, BPAI Appeal No. 2005-1340, and that proceeding may have a bearing the Board's decision in the present Appeal. In addition, the Federal Circuit's decision in *In re Fisher* may also have a bearing on the Board's decision with regard to at least one of the grounds of rejection

in the present appeal. A copy of the Board's decision in Appeal No. 2005-1340, and a copy of *In re Fisher*, 412 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005) are attached hereto in the Related Proceedings Appendix.

3. Status of Claims

Claims 8 to 10 and 12 to 27 are pending. Claims 1 to 7 and 11 were canceled without prejudice to, or disclaimer of, the subject matter claimed therein, on October 10, 2000 and January 23, 2006. Claims 8 to 10 and 12 to 27 stand finally rejected under 35 U.S.C. § 112, first paragraph, and under 35 U.S.C. § 101. The Appellants appeal the rejections of claims 8 to 10 and 12 to 27.

4. Status of Amendments

The Appellants have not filed any amendments subsequent to the final rejection dated August 16, 2006.

5. Summary of Claimed Subject Matter

Independent Claim 8: The claimed subject matter of independent claim 8 is directed to a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the list of recited SEQ ID NOs, where the microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Independent Claim 14: The claimed subject matter of independent claim 14 is directed to a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid

molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of the recited SEQ ID NOs.

Independent Claim 18: The claimed subject matter of independent claim 18 is directed to a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group of the recited SEQ ID NOs.

Independent Claim 22: The claimed subject matter of independent claim 22 is directed to a microarray comprising nucleic acid sequences obtained from maize, where the microarray comprises a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group of the recited SEQ ID NOs.

Independent Claim 26: The claimed subject matter of independent claim 26 is directed to a substrate comprising nucleic acid sequences obtained from maize, where the substrate comprises a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group of the recited SEQ ID NOs.

Independent Claim 27: The claimed subject matter of independent claim 27 is directed to a microarray for high-throughput monitoring of gene expression in a corn plant, where the

microarray comprises a substrate with an array of at least 1000 oligonucleotide probes that hybridize to at least 1000 different nucleic acid molecules expressed by corn plant genes where at least 10% of the nucleic acid molecules are at least 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of the recited SEQ ID NOs, or the complements thereof, and where the microarray is effective for analyzing gene expression in corn lines including corn lines derived from the *Zea mays* genotype RX601.

A copy of the claims on appeal is attached hereto in the Claims Appendix.

6. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed in this Appeal are:

(a) pending claims 8 to 10 and 12 to 27 stand rejected under 35 U.S.C. §§ 101 and 112 because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility; and

(b) pending claims 8 to 10 and 12 to 27 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement.

7. Argument

A. Summary of Appellants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Appellants have met their part of the bargain – they have disclosed microarrays and substrates comprising nucleic acid

molecules expressed during anthesis in maize plants which, in their current form, provide at least one specific benefit to the public, for example use to monitor gene expression during anthesis. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed microarrays provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed microarrays for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Appellant has provided an adequate description of the claimed microarrays having the recited nucleic acid molecules that demonstrates Appellant's possession of the claimed invention. The genera of claimed microarrays, for example, the genus of microarrays comprising the recited nucleic acid sequences, have been described by the recitation of common structural features, *e.g.,* the nucleotide sequence of SEQ ID NO: 5776, etc, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Appellant had possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Claimed Microarrays Have Utility

The Examiner rejected pending claims 8 to 10 and 12 to 27 under 35 U.S.C. § 101, because the claimed invention allegedly "lacks patentable utility." *Final Office Action* mailed August 16, 2006 at page 2.

The specification provides a specific, substantial, and credible utility for the claimed microarrays. For example, the specification clearly asserts that the microarrays of the present

invention can be used for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression of such genes. *See, e.g.,* specification at page 56, lines 5 to 17, page 59, line 18 through page 60, line 16, page 61, lines 4 to 10 and page 92, lines 8 to 14. The skilled artisan would have understood the utility of the claimed microarray based on such a disclosure. In addition, the claimed microarray allows for customization such that the skilled artisan can design the claimed microarrays to a given set of requirements determined by the artisan. One of ordinary skill in the art would recognize that the claimed microarrays have utility, for example, to determine whether a biological sample contains maize nucleic acid sequences or hybridizing homologues upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner argues, however, that "[t]he claimed combination of nucleic acids comprised on a substrate or as a microarray is not supported by a substantial utility because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid." *Final Office Action* at page 4. The Examiner asserts that "[u]nless the array, or the probes found on the array (i.e. nucleic acids), are specific for a certain disease, condition, or certain agronomically significant traits, the nucleic acids [are] only useful for conducting further research to find a substantial utility." *Id.* at page 5. The Examiner appears to support this assertion by alleging that there "is no evidence that LIB189 is a subtractive library", *Id.* at page 4, and that "there is no evidence that any of the nucleic acids comprised on the claimed microarray are expressed only at the time of 'anthesis,' only in leaf tissue, or only in *Zea mays* plant having the RX601 genotype." *Id.* at page 5.

The Examiner has provided no support for the assertion that the genes can be expressed only during a given condition or must be specific to a certain disease or agronomic trait to satisfy the utility requirement. As previously stated, the claimed microarrays contain nucleic acid sequences from maize corresponding to genes expressed during anthesis. As such, the claimed microarrays can be used, for example, for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression of such genes regardless of whether the sequences are expressed exclusively during anthesis.

The Examiner further appears to argue that all nucleic acid molecules are expressed during anthesis. The Examiner states that "[w]hile Applicants can state that the nucleic acids of the claimed microarray was expressed during anthesis, such statement can be made about any nucleic acid. All nucleic acids are expressed at some point." *Id.* at pages 9 to 10. This statement is incorrect in at least two ways. First, not every nucleic acid is expressed during anthesis. Second, all nucleic acids are <u>not</u> expressed at some point. Indeed, the differential and non-expression of nucleic acids is an important component of gene regulation and differentiation of one organism from another. For instance it is a well-known fact that the DNA of human beings is 90+ percent identical to the DNA of chimpanzees. Differential and non-expression of genes is a critical reason why human beings are different from chimpanzees.

The Examiner admits that "one of skill in the art would recognize that a unique expression (e.g., overexpression, underexpression, or expressed at some point while absent during some point) of a particular nucleic acid for a particular phenotype, condition or state <u>would have an immediate applicable utility</u>" *Id.* at page 10, emphasis added. The Examiner,

however, states that "the microarray of the claimed invention does not disclose such knowledge." *Id.* The Appellants respectfully disagree because the nucleic acids of the claimed microarray were expressed during anthesis, which is a "particular phenotype, condition or state". Using the Examiner's own admission, the nucleic acids "have an immediate applicable utility".

Moreover, the Examiner appears to focus on the utility of the individual nucleic acid sequences contained on the claimed microarray. Claims must be considered as a whole in determining compliance with § 101. *Diamond v. Diehr*, 450 U.S. 175, 188, 209 U.S.P.Q. 1, 9 (1981). It is inappropriate to dissect claims and consider some elements while ignoring others. *Id.* The rejection of the claims continues to focus on the function of the proteins encoded by individual nucleic acid sequences recited in the Markush group on the claimed microarray. The Appellants respectfully submit that they are not claiming recited nucleic acid sequences in the abstract. The Appellants have disclosed nucleic acid sequences obtained from maize. The claims however are not limited to the nucleic acid sequences, but are directed as a whole to microarrays that comprise, *inter alia*, various nucleic acid sequences selected from the recited Markush group. Accordingly, the Examiner's arguments that the patentability of the claims is based on the utility of individual nucleic acid sequences alone is improper.

The Examiner responds by stating "that whether the mere isolation of expressed nucleic acid sequences (ESTs) in an collective form, absent a substantial utility, is the issue central to determining whether the claims meet the utility requirement." *Final Office Action* at page 8. This statement provided validation to the Appellants' position that the Examiner continues to be focused on the nucleic acid sequences, rather than on the claimed invention as a whole. Indeed, the Examiner pejoratively dismisses the claimed invention as "the mere isolation of expressed

nucleic acid sequences (ESTs) in an collective form". *Id.*, emphasis added. The Examiner goes on to state that "(t)he claims are drawn to a product. The product, as the claims recite, are defined by SEQ ID Numbers and the patentability is based on the SEQ ID Numbers." *Id.* at page 12. This statement further reinforces the Appellants' position that the Examiner is not addressing the claimed invention as a whole.

Moreover, the Office has acknowledged that microarrays in general have a specific and substantial utility by way of their "utility for being able to analyze a plurality of nucleic acid samples simultaneously." *Examiner's Answer* dated May 23, 2003 at page 8 and *see,* Board Decision mailed November 22, 2005 at page 10. The claimed microarrays similarly have the ability to analyze a large number of nucleic acid molecules in a sample simultaneously, for example, for the presence of maize nucleic acid sequences expressed during anthesis within the sample. The skilled artisan would recognize that such microarrays can be useful in identity preservation programs.

In addition, the Office has acknowledged that the in the Fodor and Pirrung patents, "the skilled artisan is free to select the relevant reagent (*e.g.*, nucleic acid) of their choice to attach to the array." Board Decision at page 10. Claims 8 and 12 to 27 similarly allow the skilled artisan to design or customize a particular microarray tailored to the specific requirements of the artisan. The claimed microarrays can be tailored to a given set of requirements while providing sequences selected from the recited Markush group that can act, for example, as a control to test technical performance of the array.

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial

utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). The Appellants have met this part of the bargain – the present specification discloses microarrays which, in their current form, provide at least one specific benefit to the public, for example, use to analyze biological samples for the presence of maize nucleic acid sequences. *See, e.g.*, *Specification* at page 59, lines 18 to 24. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose "that an invention is useful to the public as disclosed in its current form." *Id.* at 1371. Second, the Court further noted that the specification "also show that that claimed invention can be used to provide a well-defined and particular benefit." *Id.* The Appellants have provided microarrays which are shown in the specification to be useful in analyzing biological samples for the presence of maize nucleic acid sequences. Such a use is sufficient to satisfy the utility standard. *Id.*

The specification discloses specific and substantial uses for the claimed microarrays, including use to analyze biological samples for the presence of maize nucleic acid sequence homologues (*see, e.g.*, *Specification* at page 59, line 18 through page 60, line 26, and page 21, lines 11 to 17) and in high-throughput monitoring of gene expression in a corn plant (*see, e.g.*, *Specification* at page 59, line 25 through page 60, line 16 and page 61, lines 4 to 10). Moreover, because one skilled in the art may design a microarray comprising a substrate with a variety of molecules characterized by different sequences from the recited Markush group, *see, e.g.*, claim

8, the claimed microarrays may be varied or customized to identify or screen for a particular nucleic acid molecule or molecules as designated by the designer. *See, e.g.*, Petition under 37 C.F.R. § 1.144, filed January 10, 2003, at pages 7 to 10. The Examiner argues that this utility, like many of the asserted utilities, is not specific or substantial. *Final Office Action* at page 5, but does not provide any support (legal or factual) for the proposition that screening large populations of nucleic acids using the claimed microarrays is not a legally sufficient utility.

One of ordinary skill in the art would recognize that the claimed microarrays have utility, for example, to analyze biological samples for the presence of maize nucleic acid sequences or for high-throughput monitoring of gene expression in a corn plant. These utilities are immediately apparent for the claimed microarrays without further research. The claimed microarrays have been asserted to be useful in analyzing biological samples for the presence of maize molecules and for high-throughput monitoring of gene expression in a corn plant. These utilities provide a well-defined and particular benefit, *e.g.*, to identify maize nucleic acid molecules in a sample, and these utilities are immediately useful to the public as disclosed in their current form. Accordingly, the assertion of the use of the claimed microarrays to analyze such samples satisfies the utility requirement of 35 U.S.C. § 101.

The claimed microarrays have been asserted to be useful in analyzing biological samples for the presence of maize molecules and for high-throughput monitoring of gene expression in a corn plant. These utilities provide a well-defined and particular benefit, *e.g.*, to identify maize nucleic acid molecules in a sample, and these utilities are immediately useful to the public as disclosed in their current form. The Appellants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

In conclusion, the Appellants respectfully submit that the assertion of the uses of the claimed microarrays fully satisfy the utility requirement of 35 U.S.C. §§ 101 and 112, first paragraph. Therefore, the Appellants respectfully request that the Board reverse the rejection of claims 8 to 10 and 12 to 27 under 35 U.S.C. §§ 101 and 112, first paragraph.

C. The Claimed Microarrays Are Enabled by the Specification

The enablement of the claimed microarrays has been challenged. Claims 8-10 and 12-27 were rejected as not enabled by the specification, because the recited nucleic acid molecules allegedly lack utility and therefore cannot be enabled. *Final Action* at page 17. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

The Examiner rejected pending claims 8 to 10 and 12 to 27 under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification

in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention". *Final Office Action* at page 17.

The Examiner admits that the SEQ ID Numbers of the Markush group in the claims meet the written description provision of 35 U.S.C. § 112, first paragraph. *Final Office Action* at page 18. The Examiner argues, however, that

> claims 8-10 and 12-27 recite nucleic acid (*sic*) comprising the claimed SEQ ID Numbers. Because it is not apparent from the specification that the claimed SEQ ID Numbers contain a full open reading frame, the claimed nucleic acids of SEQ ID Numbers read on cDNAs of full open reading frame. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompasses by the claim.

Id. at page 18. The Examiner goes on to add "the full breadth of the claims not only embrace the above-discussed embodiment [*i.e.*, a microarray comprising the recited nucleic acid molecules] but also [a] microarray "comprising at least 250 nuclecotides" that are complimentary [*sic*] to a collection of SEQ ID Numbers. Hence, the full-breadth of the claims read on microarray comprising full-length gene which are complementary to SEQ ID Numbers, the genes of which comprising additional sequences in addition to the 250 complementary nucleotides." *Id.* at page 20.

In short, the Examiner argues that because the specification does not explicitly state that the SEQ ID NOs do not contain full open reading frames, the claimed nucleic acids of SEQ ID NOs must automatically read on cDNAs with full open reading frames, and "(t)he specification clearly demonstrates that the nucleic acid of the SEQ ID Numbers are ESTs, and no evidence is shown that they have identified the entire open-reading frame of from which these ESTs are

derived from (*sic*)." *Id.* The Appellants respectfully disagree. The claimed microarrays do not recite open reading frames, and thus need not describe them. Moreover, the skilled artisan would be able to identify open reading frames within the recited sequences using methods known in the art. The Appellants have fully described each SEQ ID NO by setting forth its nucleotide sequence.

In addition, the Examiner argues that because the claims use the transitional phrase "comprising" there is insufficient written description in the specification. This cannot be a proper basis for a written description rejection of a "comprising" claim. If it were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention – and the Examiner appears to assert that each nucleic acid molecule within the genus must be described by its complete structure. Not only are these assertions unfounded, the specification demonstrates to one skilled in the art that the Appellants were in fact in possession of the claimed microarrays comprising the claimed genera of nucleic acid molecules.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand

that the Appellants had possession a microarray comprising nucleic acid sequences selected from the group consisting of SEQ ID NOs: 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc., and their complements, and therefore, the claimed invention.

The Appellants have provided the nucleotide sequences recited by the claims, *e.g.*, SEQ ID 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc., and have disclosed microarrays comprising such sequences, and have thus established possession of the claimed invention. Moreover, the present application describes more than just microarrays including the nucleotide sequences required by the claims. For example, it describes vectors comprising the claimed nucleic acid molecules, *see, e.g., Specification* at page 67, line 14 through page 74, line 11, as well as plants transformed by the nucleic acid molecules of the present invention. *See, e.g., Specification* at page 74, line 16 to page 82, line 24). Thus, the fact that the claims at issue are intended to cover microarrays comprising nucleic acid molecules that include the recited sequences joined with additional sequences, or complements of the recited sequences does not mean that the Appellants were any less in possession of the nucleic acid molecules of the claimed microarrays.[1] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

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[1] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

The present application describes more than just the claimed microarrays and the nucleic acid sequences of the claimed microarrays. For example, it describes how to make the nucleotide sequences and the libraries from which they were originally purified (specification at page 33, line 6 through page 39, line 25, and Examples 1 and 2). In addition, one of ordinary skill in the art has the ability to make and use the claimed microarrays based on the disclosure of the present specification, as well as envision a nucleic acid molecule that is complementary to any of the nucleic acid molecules of the claimed microarrays. Furthermore, the addition of extra nucleotides or detectable labels to the sequences present on the claimed microarrays is readily envisioned by one of ordinary skill in the art upon reading the present specification,[2] in particular at page 17, lines 20 to 24 (describing sequences with labels to facilitate detection); at page 62, line 8 through page 63, line 2 (describing site-directed mutagenesis of nucleic acid molecules); and at page 86, line 22 to page 87, line 3 (citing references describing the construction, manipulation and isolation of macromolecules). Moreover, it is well established that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA 1981)).

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) as recently

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[2] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

amplified by *Capon v. Eshhar*, 418 F.3d 1349, 76 U.S.P.Q. 1078 (Fed. Cir. 2005). The Appellants have satisfied that test for written description. The claimed microarrays comprise combinations or collections of several genera of nucleic acid molecules. Each genus of nucleic acid molecules on the claimed microarray comprise sequences that are complementary to at least one particular enumerated nucleotide sequence, for example, SEQ ID NOs: 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc. The Appellants have disclosed common structural features for each genus of nucleic acid molecules, for example, SEQ ID NO: 5776. The respective common structural feature (*i.e.,* the complement or complements to a nucleotide sequence or sequences recited in the present claims) is shared by every nucleic acid molecule which may be included in a claimed microarray comprising a particular nucleic acid molecule; and the nucleic acid sequence of that nucleic acid molecule distinguishes the members of that genus of nucleic acid molecules from non-members.

One skilled in the art would clearly know if a microarray comprises a substrate with a surface comprising 1000 nucleic acid molecules or more where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising any one or more of the recited nucleotide sequences. The fact that a nucleic acid molecule may comprise additional sequences, variations, or a full-length cDNA is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

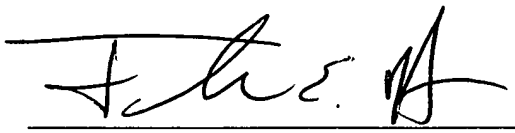
In sum, the specification demonstrates that the Appellants had possession of the claimed microarrays, and have provided an adequate description of the claimed genera of microarrays comprising nucleic acid molecules that are complementary to a nucleic acid molecule comprising

one of the recited SEQ ID NOs. Therefore, the specification fully satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, and the Appellants respectfully request that the Board reverse the rejection of claims 8 to 10 and 12 to 27 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing, the Appellants respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



Date: January 16, 2007

Thomas E. Holsten (Reg. Atty. No. 46,098)
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CLAIMS APPENDIX

Claims 1 to 7. (Canceled)

Claim 8. A microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO:

6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, and SEQ ID NO: 6181, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 9. A microarray according to claim 8 where at least 75% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from said group.

Claim 10. A microarray according to claim 8 where at least 95% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from said group.

Claim 11. (Canceled)

Claim 12. The microarray according to claim 8, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 13. The microarray according to claim 12, wherein said nucleic acid molecules are derived from LIB189.

Claim 14. A microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule

comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, SEQ ID NO: 6181 SEQ ID NO: 6188, SEQ ID

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8624, SEQ ID NO: 8625, SEQ ID NO: 8631, SEQ ID NO: 8632, SEQ ID NO: 8639, SEQ ID NO: 8644, and SEQ ID NO: 8665.

Claim 15. The microarray according to claim 14, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 16. The microarray according to claims 15, wherein said nucleic acid molecules are derived from LIB189.

Claim 17. The microarray according to claim 14, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 18. A microarray comprising a substrate with a surface having at least 1000 nucleic acid molecules where more than 10% of said nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO:

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Claim 19. The microarray according to claim 18, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 20. The microarray according to claim 19, wherein said nucleic acid molecules are derived from LIB189.

Claim 21. The microarray according to claim 18, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 22. A microarray comprising nucleic acid sequences obtained from maize, wherein said microarray comprises a substrate with a surface having at least 1000 nucleic acid molecules

where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ

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ID NO: 7559, SEQ ID NO: 7563, SEQ ID NO: 7565, SEQ ID NO: 7572, SEQ ID NO: 7576, SEQ ID NO: 7590, SEQ ID NO: 7592, SEQ ID NO: 7594, SEQ ID NO: 7596, SEQ ID NO: 7602, SEQ ID NO: 7612, SEQ ID NO: 7617, SEQ ID NO: 7618, SEQ ID NO: 7622, SEQ ID NO: 7624, SEQ ID NO: 7627, SEQ ID NO: 7631, SEQ ID NO: 7632, SEQ ID NO: 7644, SEQ ID NO: 7646, SEQ ID NO: 7655, SEQ ID NO: 7657, SEQ ID NO: 7659, SEQ ID NO: 7677, SEQ ID NO: 7682, SEQ ID NO: 7685, SEQ ID NO: 7690, SEQ ID NO: 7694, SEQ ID NO: 7697, SEQ ID NO: 7701, SEQ ID NO: 7702, SEQ ID NO: 7703, SEQ ID NO: 7707, SEQ ID NO: 7708, SEQ ID NO: 7711, SEQ ID NO: 7715, SEQ ID NO: 7718, SEQ ID NO: 7721, SEQ ID NO: 7723, SEQ ID NO: 7724, SEQ ID NO: 7729, SEQ ID NO: 7736, SEQ ID NO: 7745, SEQ ID NO: 7749, SEQ ID NO: 7757, SEQ ID NO: 7761, SEQ ID NO: 7770, SEQ ID NO: 7772, SEQ ID NO: 7777, SEQ ID NO: 7782, SEQ ID NO: 7791, SEQ ID NO: 7795, SEQ ID NO: 7796, SEQ ID NO: 7800, SEQ ID NO: 7801, SEQ ID NO: 7802, SEQ ID NO: 7808, SEQ ID NO: 7809, SEQ ID NO: 7813, SEQ ID NO: 7818, SEQ ID NO: 7823, SEQ ID NO: 7825, SEQ ID NO: 7826, SEQ ID NO: 7827, SEQ ID NO: 7831, SEQ ID NO: 7837, SEQ ID NO: 7844, SEQ ID NO: 7845, SEQ ID NO: 7847, SEQ ID NO: 7849, SEQ ID NO: 7852, SEQ ID NO: 7856, SEQ ID NO: 7860, SEQ ID NO: 7862, SEQ ID NO: 7863, SEQ ID NO: 7865, SEQ ID NO: 7867, SEQ ID NO: 7870, SEQ ID NO: 7872, SEQ ID NO: 7880, SEQ ID NO: 7883, SEQ ID NO: 7884, SEQ ID NO: 7885, SEQ ID NO: 7886, SEQ ID NO: 7888, SEQ ID NO: 7889, SEQ ID NO: 7894, SEQ ID NO: 7895, SEQ ID NO: 7896, SEQ ID NO: 7901, SEQ ID NO: 7905, SEQ ID NO: 7908, SEQ ID NO: 7918, SEQ ID NO: 7928, SEQ ID NO: 7931, SEQ ID NO: 7937, SEQ ID NO: 7947, SEQ ID NO: 7952, SEQ ID NO: 7959, SEQ ID NO: 7962, SEQ ID NO: 7975, SEQ ID NO: 7987, SEQ ID NO: 7989, SEQ ID NO: 7992, SEQ ID NO:

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Claim 23. The microarray according to claim 22, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 24. The microarray according to claim 23, wherein said nucleic acid molecules are derived from LIB189.

Claim 25. The microarray according to claim 22, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 26. A substrate containing nucleic acid molecules obtained from maize, wherein said substrate comprises a surface having 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926,

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Claim 27. A microarray for high-throughput monitoring of gene expression in a corn plant, where said microarray comprises a substrate with an array of at least 1000 oligonucleotide probes that hybridize to at least 1000 different nucleic acid molecules expressed by corn plant genes where at least 10% of the nucleic acid molecules are at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ

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ID NO: 6778, SEQ ID NO: 6781, SEQ ID NO: 6782, SEQ ID NO: 6790, SEQ ID NO: 6792, SEQ ID NO: 6841, SEQ ID NO: 6870, SEQ ID NO: 6871, SEQ ID NO: 6886, SEQ ID NO: 6894, SEQ ID NO: 6904, SEQ ID NO: 6906, SEQ ID NO: 6923, SEQ ID NO: 6931, SEQ ID NO: 6934, SEQ ID NO: 6938, SEQ ID NO: 6939, SEQ ID NO: 6949, SEQ ID NO: 6953, SEQ ID NO: 6961, SEQ ID NO: 6965, SEQ ID NO: 6978, SEQ ID NO: 6991, SEQ ID NO: 7000, SEQ ID NO: 7002, SEQ ID NO: 7036, SEQ ID NO: 7050, SEQ ID NO: 7053, SEQ ID NO: 7062, SEQ ID NO: 7070, SEQ ID NO: 7078, SEQ ID NO: 7083, SEQ ID NO: 7096, SEQ ID NO: 7100, SEQ ID NO: 7106, SEQ ID NO: 7107, SEQ ID NO: 7134, SEQ ID NO: 7144, SEQ ID NO: 7161, SEQ ID NO: 7164, SEQ ID NO: 7178, SEQ ID NO: 7206, SEQ ID NO: 7220, SEQ ID NO: 7221, SEQ ID NO: 7224, SEQ ID NO: 7228, SEQ ID NO: 7229, SEQ ID NO: 7241, SEQ ID NO: 7246, SEQ ID NO: 7248, SEQ ID NO: 7249, SEQ ID NO: 7254, SEQ ID NO: 7261, SEQ ID NO: 7267, SEQ ID NO: 7277, SEQ ID NO: 7332, SEQ ID NO: 7338, SEQ ID NO: 7351, SEQ ID NO: 7357, SEQ ID NO: 7369, SEQ ID NO: 7378, SEQ ID NO: 7380, SEQ ID NO: 7384, SEQ ID NO: 7386, SEQ ID NO: 7395, SEQ ID NO: 7438, SEQ ID NO: 7444, SEQ ID NO: 7447, SEQ ID NO: 7461, SEQ ID NO: 7463, SEQ ID NO: 7465, SEQ ID NO: 7468, SEQ ID NO: 7478, SEQ ID NO: 7490, SEQ ID NO: 7491, SEQ ID NO: 7492, SEQ ID NO: 7509, SEQ ID NO: 7514, SEQ ID NO: 7536, SEQ ID NO: 7559, SEQ ID NO: 7563, SEQ ID NO: 7565, SEQ ID NO: 7572, SEQ ID NO: 7576, SEQ ID NO: 7590, SEQ ID NO: 7592, SEQ ID NO: 7594, SEQ ID NO: 7596, SEQ ID NO: 7602, SEQ ID NO: 7612, SEQ ID NO: 7617, SEQ ID NO: 7618, SEQ ID NO: 7622, SEQ ID NO: 7624, SEQ ID NO: 7627, SEQ ID NO: 7631, SEQ ID NO: 7632, SEQ ID NO: 7644, SEQ ID NO: 7646, SEQ ID NO: 7655, SEQ ID NO: 7657, SEQ ID NO: 7659, SEQ ID NO: 7677, SEQ ID NO: 7682, SEQ ID NO:

7685, SEQ ID NO: 7690, SEQ ID NO: 7694, SEQ ID NO: 7697, SEQ ID NO: 7701, SEQ ID NO: 7702, SEQ ID NO: 7703, SEQ ID NO: 7707, SEQ ID NO: 7708, SEQ ID NO: 7711, SEQ ID NO: 7715, SEQ ID NO: 7718, SEQ ID NO: 7721, SEQ ID NO: 7723, SEQ ID NO: 7724, SEQ ID NO: 7729, SEQ ID NO: 7736, SEQ ID NO: 7745, SEQ ID NO: 7749, SEQ ID NO: 7757, SEQ ID NO: 7761, SEQ ID NO: 7770, SEQ ID NO: 7772, SEQ ID NO: 7777, SEQ ID NO: 7782, SEQ ID NO: 7791, SEQ ID NO: 7795, SEQ ID NO: 7796, SEQ ID NO: 7800, SEQ ID NO: 7801, SEQ ID NO: 7802, SEQ ID NO: 7808, SEQ ID NO: 7809, SEQ ID NO: 7813, SEQ ID NO: 7818, SEQ ID NO: 7823, SEQ ID NO: 7825, SEQ ID NO: 7826, SEQ ID NO: 7827, SEQ ID NO: 7831, SEQ ID NO: 7837, SEQ ID NO: 7844, SEQ ID NO: 7845, SEQ ID NO: 7847, SEQ ID NO: 7849, SEQ ID NO: 7852, SEQ ID NO: 7856, SEQ ID NO: 7860, SEQ ID NO: 7862, SEQ ID NO: 7863, SEQ ID NO: 7865, SEQ ID NO: 7867, SEQ ID NO: 7870, SEQ ID NO: 7872, SEQ ID NO: 7880, SEQ ID NO: 7883, SEQ ID NO: 7884, SEQ ID NO: 7885, SEQ ID NO: 7886, SEQ ID NO: 7888, SEQ ID NO: 7889, SEQ ID NO: 7894, SEQ ID NO: 7895, SEQ ID NO: 7896, SEQ ID NO: 7901, SEQ ID NO: 7905, SEQ ID NO: 7908, SEQ ID NO: 7918, SEQ ID NO: 7928, SEQ ID NO: 7931, SEQ ID NO: 7937, SEQ ID NO: 7947, SEQ ID NO: 7952, SEQ ID NO: 7959, SEQ ID NO: 7962, SEQ ID NO: 7975, SEQ ID NO: 7987, SEQ ID NO: 7989, SEQ ID NO: 7992, SEQ ID NO: 7997, SEQ ID NO: 7998, SEQ ID NO: 8002, SEQ ID NO: 8006, SEQ ID NO: 8007, SEQ ID NO: 8008, SEQ ID NO: 8010, SEQ ID NO: 8015, SEQ ID NO: 8017, SEQ ID NO: 8018, SEQ ID NO: 8020, SEQ ID NO: 8022, SEQ ID NO: 8024, SEQ ID NO: 8026, SEQ ID NO: 8043, SEQ ID NO: 8048, SEQ ID NO: 8053, SEQ ID NO: 8063, SEQ ID NO: 8064, SEQ ID NO: 8066, SEQ ID NO: 8095, SEQ ID NO: 8098, SEQ ID NO: 8099, SEQ ID NO: 8103, SEQ ID NO: 8126, SEQ ID NO: 8145, SEQ

ID NO: 8153, SEQ ID NO: 8155, SEQ ID NO: 8157, SEQ ID NO: 8161, SEQ ID NO: 8171, SEQ ID NO: 8175, SEQ ID NO: 8180, SEQ ID NO: 8184, SEQ ID NO: 8192, SEQ ID NO: 8198, SEQ ID NO: 8199, SEQ ID NO: 8201, SEQ ID NO: 8212, SEQ ID NO: 8216, SEQ ID NO: 8222, SEQ ID NO: 8224, SEQ ID NO: 8225, SEQ ID NO: 8228, SEQ ID NO: 8238, SEQ ID NO: 8242, SEQ ID NO: 8256, SEQ ID NO: 8259, SEQ ID NO: 8274, SEQ ID NO: 8277, SEQ ID NO: 8278, SEQ ID NO: 8289, SEQ ID NO: 8292, SEQ ID NO: 8297, SEQ ID NO: 8301, SEQ ID NO: 8317, SEQ ID NO: 8329, SEQ ID NO: 8333, SEQ ID NO: 8334, SEQ ID NO: 8335, SEQ ID NO: 8351, SEQ ID NO: 8355, SEQ ID NO: 8374, SEQ ID NO: 8377, SEQ ID NO: 8379, SEQ ID NO: 8383, SEQ ID NO: 8394, SEQ ID NO: 8406, SEQ ID NO: 8447, SEQ ID NO: 8452, SEQ ID NO: 8455, SEQ ID NO: 8458, SEQ ID NO: 8465, SEQ ID NO: 8468, SEQ ID NO: 8472, SEQ ID NO: 8479, SEQ ID NO: 8482, SEQ ID NO: 8487, SEQ ID NO: 8492, SEQ ID NO: 8500, SEQ ID NO: 8503, SEQ ID NO: 8507, SEQ ID NO: 8511, SEQ ID NO: 8512, SEQ ID NO: 8517, SEQ ID NO: 8518, SEQ ID NO: 8529, SEQ ID NO: 8530, SEQ ID NO: 8538, SEQ ID NO: 8542, SEQ ID NO: 8553, SEQ ID NO: 8554, SEQ ID NO: 8556, SEQ ID NO: 8560, SEQ ID NO: 8568, SEQ ID NO: 8569, SEQ ID NO: 8578, SEQ ID NO: 8579, SEQ ID NO: 8580, SEQ ID NO: 8583, SEQ ID NO: 8584, SEQ ID NO: 8585, SEQ ID NO: 8587, SEQ ID NO: 8590, SEQ ID NO: 8601, SEQ ID NO: 8607, SEQ ID NO: 8611, SEQ ID NO: 8616, SEQ ID NO: 8624, SEQ ID NO: 8625, SEQ ID NO: 8631, SEQ ID NO: 8632, SEQ ID NO: 8639, SEQ ID NO: 8644, and SEQ ID NO: 8665 or the complement thereof; and wherein said microarray is effective for analyzing gene expression in corn lines including corn lines derived from the *Zea mays* genotype RX601.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

1. BPAI Appeal No. 2005-1340; and
2. *In re Fisher*, 412 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005).

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DANE K. FISHER, and RAGHUNATH V. LALGUDI

Appeal No. 2005-1340
Application No. 09/394,745

HEARD: August 23, 2005

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8-11, which are all the claims pending in the application.

Claim 11 is illustrative of the subject matter on appeal and is reproduced below:

11. A microarray comprising nucleic acid molecules that are comprised of different sequences and at least about 250 nucleotide residues, wherein said nucleic acid molecules comprise nucleic acid sequences complementary to SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896,

SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, and SEQ ID NO: 6181.

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

GROUNDS OF REJECTION

Claims 8-11 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

Claims 8-11 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an adequate written description of the claimed invention.

We affirm the utility rejections under 35 U.S.C. § 101 and § 112, first paragraph. Having disposed of all claims on appeal, we do not reach the merits of the written description rejection.

PROCEDURAL BACKGROUND

The application was originally filed with seven claims. On October 10, 2000, appellants cancelled all pending claims and submitted claims 8-11. Claim 8, entered into the record on October 10, 2000, is similar to amended claim 8 now before us on appeal; one notable difference, however, is that the Markush grouping of nucleic acid molecules set forth in original claim 8 recited 497 nucleotide sequences by SEQ ID NO. On December 19, 2000, the examiner entered a Restriction Requirement into the record, which required appellants to select a patentably distinct group of invention from the group consisting of (I) claims 8-10; and (II) claim 11 for examination on the merits. In addition, as we understand the Restriction Requirement, if appellants elected Group I, they were further required to identify a defined group of nucleic acid molecules from the Markush grouping set forth in claim 8, for examination on the merits. In response, appellants elected, with traverse, the invention of Group I, claims 8-10, and the first 100 nucleic acid molecules set forth in original claim 8.[1] See

[1] At page 3 of the Office Action mailed September 11, 2002, the examiner explains "the actual combination of 'one hundred' SEQ ID Numbers was selected by Applicants, and was not required by the [e]xaminer. Applicants were requested to elect a single combination of nucleic acids (see Office Action mailed on December 19, 2000, on page 3) to which [a]pplicants have elected the 'first one hundred' SEQ ID Numbers as the elected combination ([a]pplicants' response on page 3, Paper No. 6, April 17, 1001). In other words, [a]pplicants could have elected all of the recited SEQ ID Numbers as the combination to be examined. However, it was [a]pplicants who have decided to elect the first 100 SEQ ID Numbers as the elected combination."

Response, entered April 17, 2001. On December 6, 2001, appellants clarified the record by specifically reciting the exact nucleic acid molecules elected.

On March 18, 2002, the examiner withdrew the Restriction Requirement as it relates to Groups I and II, accordingly claims 8-11 where examined on their merits. We note, however, the examiner expressly stated (Paper No. 11, mailed March 18, 2002), "the examination of SEQ ID Numbers will not go beyond the 100 SEQ ID Numbers" elected by appellants for examination on the merits. On June 18, 2002, appellants amended claim 8; among other things, this amendment limited the originally filed Markush grouping of nucleic acid molecules to the 100 sequences elected by appellants.[2]

Upon review of the record, the Restriction Requirement was in dispute throughout prosecution before the examiner, and into the appeal stage. See e.g., Supplemental Brief, received June 30, 2003, page 2. As we understand appellants' arguments, despite the fact that they amended claim 8 to include only the elected nucleic acid molecules, they argue that the original requirement to elect a set of nucleic acids was improper. Nevertheless, on page 2 of the Supplemental Answer, mailed November 12, 2004, the examiner withdrew the Restriction Requirement relating to the selection of a particular set of nucleic acid molecules. This procedural action on the part of the examiner, however, had no effect on the scope of amended claim 8 as it now appears on this record.

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[2] In addition, we note that appellants' amendment to claim 8 replaced the term "having" as it appeared after the term "[a] microarray" in line one of the claim with the term "comprising". This amendment is consistent with the examiner's construction of the term "having" as it appeared in the originally filed claim 8. See, page 3, Office Action mailed March 18, 2002, "[c]laims 8-10 recite the phrase, 'molecule having a sequence.' For the purpose of prosecution, the phrase is assumed to be open-ended and thus reading on the phrase, 'molecule comprising a sequence.'"

Further, we note there is no evidence of record that subsequent to the examiner's withdrawal of the species election appellants attempted to introduce a new claim, or amend claim 8, to reintroduce the remaining 397 non-elected nucleic acid molecules back into the claim.

In the end, as it appears before us on appeal, there is no restriction requirement of record in the application; and there is no pending claim on appeal that includes a Markush grouping of 497 SEQ ID NOs. as was set forth in claim 8 as originally filed. Accordingly, while we have considered appellants' arguments as presented in the Supplemental Brief relating to the failure of the examiner to examine a claim directed to a microarray comprising, inter alia, a Markush grouping of 497 SEQ ID NOs., there is no pending claim on appeal that includes such a grouping. We also note that the 497 nucleic acid molecules set forth in originally presented claim 11 was not subject to a Restriction Requirement. See, e.g., Restriction Requirement (mailed December 19, 2000, page 3), "[i]f group 1 (claims 8-10) is selected, examination will be restricted to only the elected combination." The Restriction Requirement makes no mention of the application of this "species" election to any of the 497 SEQ ID NOs. listed in original claim 11. Nevertheless, appellants subsequently amended (see appellants' amendment received June 18, 2002) claim 11 to limit the group of SEQ ID NOs. to the 100 SEQ ID NOs. presented in claim 11 on appeal.

CLAIM GROUPING

According to appellants (Brief, received March 13, 2003, page 2), "[t]he patentability of claims 8-11 is addressed together...." Accordingly, we limit our discussion to representative independent claim 11. Claims 8-10 will stand or fall together with claim 11.

CLAIM CONSTRUCTION

Claim 11 is drawn to a microarray comprising nucleic acid molecules (ESTs) that are comprised of different sequences. As we understand claim 11, these nucleic acid molecules (1) are at least about 250 nucleotide residues in length[3], and (2) comprise nucleic acid sequences complementary[4] to nucleic acid molecules represented by the Markush grouping of 100 SEQ ID NOs. recited in claim 11. See e.g., Supplemental Answer, page 4: claim 11 is "drawn to a microarray comprising nucleic acid molecules, the nucleic acid molecules of which are at least 250 residues in length and complementary to nucleic acid molecules represented by their SEQ ID Numbers."

As to the SEQ ID NOs. set forth in claim 11, we note that according to appellants' specification (page 92, lines 13-14), "SEQ ID NO: 5746 through SEQ

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[3] See e.g., appellants' specification, page 16, lines 20-25 "[a]gents of the present invention include nucleic acid molecules and more specifically EST nucleic acid molecules or nucleic acid fragment molecules thereof. Fragment EST nucleic acid molecules may encode significant portion(s) of, or indeed most of, the EST nucleic acid molecule. Alternatively, the fragments may comprise smaller oligonucleotides (having from about 15 to about 250 nucleotide residues, and more preferably, about 15 to about 30 nucleotide residues)."

[4] According to appellants' specification (page 18, lines 11-13), "the molecules are said to be 'complementary' if they can hybridize to one another with sufficient stability to permit them to remain annealed to one another under conventional 'high-stringency' conditions."

ID NO: 8666 are from [the] LIB189" cDNA library. As appellants' specification explains (page 92, lines 8-13), the LIB189 cDNA library was prepared from leaf tissue harvested at anthesis from field grown Zea mays genotype RX601 plants that "were open pollinated plants in a field (multiple row) setting."

DISCUSSION

Utility:

The examiner rejected all of the claims as lacking patentable utility.[5] Initially, we note that the claimed microarrays contain nucleic acid molecules (ESTs) isolated from the LIB189 cDNA library, which was prepared from leaf tissue harvested at anthesis from field grown Zea mays genotype RX601 plants.[6] There is no evidence on this record that LIB189 is a subtractive cDNA library, wherein nucleic acid molecules from maize tissue other than leaf tissue, from developmental stages other than anthesis, and/or from Zea mays plants other than genotype RX601 is subtracted (removed) from the library. Thus, as we understand claim 11, the nucleic acid molecules associated with the claimed microarray represent 100 randomly selected nucleic acid molecules isolated from

[5] The examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. See Supplemental Answer, page 5. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

[6] Accordingly, we disagree with appellants' assertion (first Brief, page 10), "[t]he nucleic acid molecules of the claimed microarray are isolated, for example, from various samples derived from Zea mays such as ear tissue, kernel tissue, mature pollen, etc...." There is no doubt that appellants' specification (pages 91-99), discloses nucleic acid molecules isolated from cDNA libraries produced from different parts of Zea mays plants. There is, however, no requirement in the claims before us on appeal, or in claims 8-11 as originally presented, that nucleic acid from these other cDNA libraries be included on the claimed microarray. Note, that the SEQ ID NOs. set forth in claims 8-11 as originally presented are from the same cDNA library, LIB189.

pooled leaf tissue isolated from Zea mays genotype RX601 at the time of anthesis. There is, however, no evidence on this record that any of these 100 randomly selected nucleic acid molecules are expressed only at the time of "anthesis," only in leaf tissue, or only in a Zea mays plant having the RX601 genotype.

While, appellants provide SEQ ID NOs for these 100 nucleic acid molecules, appellants fail to identify any other characteristic of these nucleic acid molecules. As the examiner points out (Supplemental Answer, page 4), "[t]he specification identifies these SEQ ID Numbers as varying in length, but no open reading frame, start/stop codons, or encoded protein is identified in the specification and sequence listing of the SEQ ID Numbers." Simply put, appellants' disclosure tells a person of ordinary skill in the art nothing about any of the 100 nucleic acid molecules other than their sequence.

Accordingly, the question before us is whether appellants have satisfied the utility requirement for a claim drawn to a microarray comprising 100 nucleic acid molecules that are, but for their sequence, uncharacterized. For the following reasons, it is our opinion that appellants have not.

According to the examiner (Supplemental Answer, page 4), appellants have identified a number of utilities for the claimed microarray including screening for biological molecules, expression profiling and identifying polymorphisms. The examiner finds, however,

> [n]one of these are considered to be specific and substantial in view of the limited information provided in the specification. No traits are attributed to the combination of the recited SEQ ID Numbers. No complete gene is disclosed nor DNA

> maps/chromosomal location identified. No polymorphisms are identified within the claimed nucleic acids. The specification simply fails to disclose that any of the SEQ ID Numbers contain any polymorphism. Even if arguendo, such polymorphisms were disclosed, a disclosure of what immediately applicable information the presence of the absence of such polymorphisms would provide to a skilled practitioner would be required to which the specification does not provide.

Id. In addition the examiner finds (Supplemental Answer, page 5),

> [f]urther research and experimentation would be required to identify a full length sequence that comprise[s] the claimed SEQ ID Numbers. Further research and experimentation would also be required to determine any associated traits and/or function(s) encoded. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context of use.

Appellants make the following arguments:

I. Pirrung[7] and Fodor[8]:

As we understand appellants' arguments (Brief, page 5), Pirrung and Fodor demonstrate that those of ordinary skill in the art would understand that the microarray of claim 11 is useful in processes that included "screening for biological activity, determining relative binding affinity for a molecule bound to the claimed microarray and creating a gradient of claimed nucleotide sequences in differing concentrations." Fodor's invention is directed at an array of oligonucleotides on a solid substrate. See e.g., Title and claims 1 and 7. There is no doubt that Fodor discloses (column 10, lines 28-30) that such an array can be used to screen for biological activity. We note, however, that in contrast to appellants' claimed invention, the array set forth in Fodor's claims is not limited

[7] Pirrung et al. (Pirrung) 5,143,854 Sep. 1, 1992

to any particular nucleic acid molecules. The same is true of the invention set forth in Pirrung's claims. Thus, in each of Fodor and Pirrung, the skilled artisan is free to select the relevant reagent (e.g., nucleic acid) of their choice to attach to the array. In contrast, appellants' claimed invention is directed to a microarray that comprises specific nucleic acid molecules identified by SEQ ID NO. Accord, Supplemental Answer, page 9. Therefore, the question is not whether microarrays are generally useful; to the contrary, the question is whether appellants have satisfied the utility requirement for a very specific microarray that comprises 100 nucleic acid molecules (ESTs) identified by SEQ ID NO., as set forth in appellants' claim 11.

Accordingly, to the extent that appellants assert that microarrays in general may have utility as demonstrated by Pirrung and Fodor, we agree. To the extent that appellants assert that Pirrung and Fodor demonstrate that the specific microarray set forth in appellants' claim 11 is useful, we disagree. In our opinion, the utility of a microarray is dependent on the reagent, in this case the nucleic acid molecules, associated with the microarray. In this regard, appellants assert (First Brief, page 10), the microarray of claim 11 "allow[s] one of ordinary skill in the art to design or customize a particular microarray tailored to the specific requirements of the artisan himself." While this may be true of the microarrays taught by Pirrung and Fodor, it is not true for the microarray set forth in appellants' claim 11. The microarray of appellants' claim 11 requires that the nucleic acid molecules comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, contrary to appellants' assertion, a person of

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[8] Fodor et al. (Fodor) 5,445,934 Aug. 29, 1995

ordinary skill in the art wishing to use the microarray of appellants' claim 11 is confined to the use of nucleic acid molecules that comprise nucleic acid sequences complementary to the recited SEQ ID NOs. Thus, the utility of the microarray set forth in appellants' claim 11 is dependent on the nucleic acid molecules associated with the microarray, specifically those that comprise nucleic acid sequences complementary to the recited SEQ ID NOs. However, as discussed above, the only information appellants have disclosed about these nucleic acids is their SEQ ID NOs. We also disagree with appellants' assertion (Brief, page 7), "[t]he claimed microarrays of the present invention are comprised of nucleic acid molecules isolated from various tissue of Zea mays (e.g., ear tissue, pollen, kernel tissue, anther tissue, etc.)...." As discussed above, the microarray of claim 11 comprises nucleic acid molecules isolated from leaf tissue.

Therefore, we look to the remainder of appellants' arguments with an eye toward the significance of the 100 nucleic acid molecules that are required components of the microarray set forth in appellants' claim 11. Specifically, the microarray set forth in appellants' claim 11, wherein the only information appellants have disclosed regarding the nucleic acid molecules on the microarray is their sequences.

II. Asserted Utilities:

According to appellants (Brief, pages 5-6, footnotes omitted), the claimed microarrays are useful (a) in screening for biological molecules, (b) as

hybridization probes for expression profiling, (c) in screening for biological activity, (d) determining relative binding affinity for a molecule bound to the claimed microarray, (e) creating a gradient of claimed nucleotide sequences in differing concentrations, and (f) to measure the level of mRNA in a sample. In response the examiner asserts (second Answer, page 11),

> [a]ppellants merely isolated the nucleic acids and immobilized them on the microarrays' substrate. Appellants have not tested, evaluated, or calibrated the claimed microarrays for any particular use. Therefore, an expression profiling assay using the claimed microarray would not have any meaning absent some correlation to an immediate benefit. An artisan would not know why a particular microarray comprising the claimed set of nucleic acid molecules should be used in a hybridization assay over another microarray comprising an entirely different set of nucleic acid molecules derived from maize plants. Therefore, an artisan would not know, previous to further experimentation, how to use the claimed microarray for a substantial use (i.e., what meaning could be derived from using the claimed microarray).

We agree.

According to page 34 of appellants' specification:

> The nucleic acid molecules and fragments thereof of the present invention are generated from the cDNA library, LIB189, prepared from Zea mays pooled leaf tissue harvested from field grown plants. Leaves are the carbohydrate factories of crop plants, therefore, the ESTs of the present invention will find great use in the isolation of a variety of agronomically significant genes, including but not limited to genes that are necessary to for [sic] the interception and transformation of light energy via photosynthesis linked with plant growth, quality and yield. Genes isolated using the disclosed ESTs would also be in pathways including but not limited to a pathway such as nitrogen metabolism linked to fruiting and mobilization and distribution of nitrogen.

As we understand appellants' specification, the claimed microarray comprising 100 nucleic acid molecules isolated from the LIB189 cDNA library is useful in the isolation of a variety of agronomically significant genes. There is, however, no

evidence on this record that any "agronomically significant genes" could be isolated using the claimed microarray. As discussed above, other than their sequence, as represented by their SEQ ID NO., appellants have provided no other characterization of the nucleic acid molecules associated with the microarray of claim 11.

At page 42 of their specification appellants disclose,

> [t]he nucleic acid molecules of the present invention may be used to isolate promoters of tissue enhanced[,] tissue specific, cell-specific, cell -type, developmentally or environmentally regulated expression profiles. Isolation and functional analysis of the 5' flanking promoter sequences of these genes from genomic libraries, for example, using genomic screening methods and PCR techniques would result in the isolation of useful promoters and transcriptional regulatory elements.

There is, however, no evidence on this record that the claimed microarray is useful in isolating a promoter or other transcriptional regulatory elements.

Appellants argue (Brief, page 11), "[t]here can be no question that one skilled in the art can use the claimed microarrays ... to detect a mutation affecting the concentration of an mRNA or the pattern of expression encoded by one or more of the nucleic acid molecules present on a claimed microarray." According to appellants (Brief, page 12), this use of the claimed microarrays "enables a plant breeder to determine the potential of the expression response affecting a particular trait based on the genetic material in the progeny of a cross." Initially, we note that, contrary to appellants' assertion, there is no evidence on this record that any of the SEQ ID NOs. would be capable of detecting a mutation that affects the concentration of an mRNA or the pattern of expression encoded by one or more of the nucleic acid molecules present on the

microarray set forth in claim 11. Further, even if one or more of the nucleic acid molecules associated with the microarray of claim 11 was capable of detecting such a mutation, appellants have failed to identify a trait associated with any of the nucleic acid molecules associated with the microarray of claim 11. Thus, contrary to appellants' assertion there is no evidence on this record that a plant breeder would be able, without further experimentation, to use the microarray of claim 11 to determine the potential of the expression response affecting a particular trait based on the genetic material in the progeny of a cross.

Appellants also assert (Brief, page 8), "[o]ther uses for the claimed microarrays are as probes for a multitude of biological molecules, such as nucleic acid homologues or transcription factors, or as a means to assay relative binding efficiency of such molecules." There is no evidence on this record that any of the nucleic acid molecules associated with the microarray of claim 11 would be capable of recognizing other "biological molecules." Further, even if they did since the nucleic acid molecules associated with the microarray of claim 11 are uncharacterized but for their sequence, it is unclear from appellants' specification what information would be derived from the binding of such a biological molecule to appellants' uncharacterized nucleic acid molecule. For example, appellants assert (Brief, page 9, footnote omitted), "the claimed microarrays can be used in real world applications ... to isolate nucleic acid molecules of plants and organisms such as alfalfa, Arabidopsis, barley, Brassica, cotton, sunflower, Phaseolus, etc." Stated differently, the uncharacterized nucleic acids associated with the microarray of claim 11 could be used to identify

nucleic acid homologues from other plants and organisms. We question the utility of using an uncharacterized nucleic acid molecule to find other nucleic acid molecules in other plants and organisms that would also be uncharacterized.

According to appellants (First Brief, page 10, footnote 6), the nucleic acid sequences associated with the microarray of claim 11 have a "common utility as gene-specific hybridization targets to quantitatively measure expression of corresponding plant genes in Zea mays." We note, however, that since the only information disclosed by appellants regarding these nucleic acid molecules is their sequence, further research would be required to determine the significance of any data obtained by quantitatively measuring the expression of a plant gene that corresponds to any nucleic acid molecule associated with the microarray of claim 11.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that

that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

On this record, claim 11 is drawn to a microarray comprising 100 nucleic acids that appear to be randomly selected from the 2,920 nucleic acid molecules identified by appellants to be present in LIB189.[9] But for their sequence appellants have disclosed no other information regarding these nucleic acid molecules. As to the utility of the nucleic acid molecules themselves, we find Fisher to be controlling. This case differs from Fisher in that appellants have placed these uncharacterized nucleic acid molecules (ESTs) on a microarray. However, for the foregoing reasons, we find that on this record appellants have not satisfied the utility requirement for a claim drawn to a microarray comprising 100 nucleic acid molecules that are, but for their sequence, uncharacterized.

Accordingly, we affirm the rejection of claim 11 under 35 U.S.C. § 101, and the enablement provision of 35 U.S.C. § 112, first paragraph. As set forth above claims 8-10 fall together with claim 11.

Written Description:

Having disposed of all claims on appeal, we do not reach the merits of the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

[9] According to appellants' specification (page 92), "SEQ ID NO: 5746 through SEQ ID NO: 8666 are from LIB189."

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT APPEALS AND INTERFERENCES

DEA/jlb

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United States Court of Appeals for the Federal Circuit

04-1465
(Serial No. 09/619,643)

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI

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Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

04-1465
(Serial No. 09/619,643)

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI,

DECIDED: September 7, 2005

Before MICHEL, Chief Judge, RADER and BRYSON, Circuit Judges.

Opinion for the court filed by Chief Judge MICHEL. Dissenting opinion filed by Circuit Judge RADER.

MICHEL, Chief Judge.

Dane K. Fisher and Raghunath Lalgudi (collectively "Fisher")[1] appeal from the decision of the U.S. Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences ("Board") affirming the examiner's final rejection of the only pending claim of application Serial No. 09/619,643 (the "'643 application"), entitled "Nucleic Acid Molecules and Other Molecules Associated with Plants," as unpatentable for lack of utility under 35 U.S.C. § 101 and lack of enablement under 35 U.S.C. § 112, first paragraph. Ex parte Fisher, App. No. 2002-2046 (Bd. Pat. App. Int. Mar. 16, 2004) ("Board Decision"). This appeal was submitted after oral argument on May 3, 2005. Because we conclude that substantial evidence supports the Board's findings that the

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[1] The real party in interest is Monsanto Technology LLC, which is owned by the Monsanto Company.

claimed invention lacks a specific and substantial utility and that the '643 application does not enable one of ordinary skill in the art to use the invention, we affirm.

I. BACKGROUND

A. Molecular Genetics and ESTs

The claimed invention relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants. The claimed sequences are commonly referred to as "expressed sequence tags" or "ESTs." Before delving into the specifics of this case, it is important to understand more about the basic principles of molecular genetics and the role of ESTs.

Genes are located on chromosomes in the nucleus of a cell and are made of deoxyribonucleic acid ("DNA"). DNA is composed of two strands of nucleotides in double helix formation. The nucleotides contain one of four bases, adenine ("A"), guanine ("G"), cytosine ("C"), and thymine ("T"), that are linked by hydrogen bonds to form complementary base pairs (i.e., A-T and G-C).

When a gene is expressed in a cell, the relevant double-stranded DNA sequence is transcribed into a single strand of messenger ribonucleic acid ("mRNA"). Messenger RNA contains three of the same bases as DNA (A, G, and C), but contains uracil ("U") instead of thymine. mRNA is released from the nucleus of a cell and used by ribosomes found in the cytoplasm to produce proteins.

Complementary DNA ("cDNA") is produced synthetically by reverse transcribing mRNA. cDNA, like naturally occurring DNA, is composed of nucleotides containing the four nitrogenous bases, A, T, G, and C. Scientists routinely compile cDNA into libraries to study the kinds of genes expressed in a certain tissue at a particular point in time.

One of the goals of this research is to learn what genes and downstream proteins are expressed in a cell so as to regulate gene expression and control protein synthesis.[2]

An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is typically generated by isolating a cDNA clone and sequencing a small number of nucleotides located at the end of one of the two cDNA strands. When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of mRNA extraction.

Claim 1 of the '643 application recites:

> A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

The ESTs set forth in SEQ ID NO: 1 through SEQ ID NO: 5 are obtained from cDNA library LIB3115, which was generated from pooled leaf tissue harvested from maize plants (RX601, Asgrow Seed Company, Des Moines, Iowa, U.S.A.) grown in the fields at Asgrow research stations. SEQ ID NO:1 through SEQ ID NO:5 consist of 429, 423, 365, 411, and 331 nucleotides, respectively. When Fisher filed the '643 application, he claimed ESTs corresponding to genes expressed from the maize pooled leaf tissue at the time of anthesis. Nevertheless, Fisher did not know the precise structure or function of either the genes or the proteins encoded for by those genes.

The '643 application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire

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[2] We have discussed the basic principles of molecular genetics more extensively in prior cases. See, e.g., In re Deuel, 51 F.3d 1552, 1554-56 (Fed. Cir. 1995); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1207-08 (Fed. Cir. 1991); In re O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988).

maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction ("PCR") process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.

B. Final Rejection

In a final rejection, dated September 6, 2001, the examiner rejected claim 1 for lack of utility under § 101. The examiner found that the claimed ESTs were not supported by a specific and substantial utility. She concluded that the disclosed uses were not specific to the claimed ESTs, but instead were generally applicable to any EST. For example, the examiner noted that any EST may serve as a molecular tag to isolate genetic regions. She also concluded that the claimed ESTs lacked a substantial utility because there was no known use for the proteins produced as final products resulting from processes involving the claimed ESTs. The examiner stated: "Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities."

The examiner also rejected the claimed application for lack of enablement under § 112, first paragraph. She reasoned that one skilled in the art would not know how to use the claimed ESTs because the '643 application did not disclose a specific and substantial utility for them.

On July 19, 2000, Fisher filed a notice of appeal with the Board.

C. Board Proceedings

The Board considered each of Fisher's seven potential uses but noted that Fisher focused its appeal on only two: (1) use for the identification of polymorphisms; and (2) use as probes or as a source for primers. As to the first, the Board found that the application failed to explain why the claimed ESTs would be useful in detecting polymorphisms in maize plants. Board Decision, slip op. at 14. The Board reasoned that "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage." Id., slip op. at 15. Thus, the Board concluded that Fisher's asserted uses for the claimed ESTs tended to the "insubstantial use" end of the spectrum between a substantial and an insubstantial utility. Id.

The Board also concluded that using the claimed ESTs to isolate nucleic acid molecules of other plants and organisms, which themselves had no known utility, is not a substantial utility. Id., slip op. at 16. Specifically, the Board noted that Fisher argued that the "claimed ESTs may be useful in searching for promoters that are only active in leaves at the time of anthesis." Id. The Board found, however, that the application failed to show that the claimed ESTs would be expressed only during anthesis or that they would be capable of isolating a promoter active in maize leaves at the time of anthesis. Id., slip op. at 18.

Additionally, the Board addressed the remaining asserted utilities, highlighting in particular the use of the claimed ESTs to monitor gene expression by measuring the level of mRNA through microarray technology and to serve as molecular markers. The Board found that using the claimed ESTs in screens does not provide a specific benefit

because the application fails to provide any teaching regarding how to use the data relating to gene expression. Id., slip op. at 21. The Board analogized the facts to those in Brenner v. Manson, 383 U.S. 519 (1966), in which an applicant claimed a process of making a compound having no known use. In that case, the Supreme Court affirmed the rejection of the application on § 101 grounds. Here, the Board reasoned: "Just as the process in Brenner lacked utility because the specification did not disclose how to use the end-product, the products claimed here lack utility, because even if used in gene expression assays, the specification does not disclose how to use SEQ ID NO: 1-5 specific gene expression data." Id., slip op. at 22. The Board offered a similar rationale for the use of the claimed ESTs as molecular markers. Id., slip op. at 24. Accordingly, the Board affirmed the examiner's rejection of the '643 application for lack of utility under § 101. The Board also affirmed the examiner's rejection of the '643 application for lack of enablement under § 112, first paragraph, since the enablement rejection was made as a corollary to the utility rejection.

Fisher timely appealed. We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(4) and 35 U.S.C. §§ 141 and 144.

II. DISCUSSION

Whether an application discloses a utility for a claimed invention is a question of fact. In re Ziegler, 992 F.2d 1197, 1200 (Fed. Cir. 1993). We consequently review the Board's determination that the '643 application failed to satisfy the utility requirement of § 101 for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) ("Because our review of the Board's decision is confined to the factual record compiled

by the Board, we accordingly conclude that the 'substantial evidence' standard is appropriate for our review of Board factfindings.").

A. Utility

1.

Fisher asserts that the Board unilaterally applied a heightened standard for utility in the case of ESTs, conditioning patentability upon "some undefined 'spectrum' of knowledge concerning the corresponding gene function." Fisher contends that the standard is not so high and that Congress intended the language of § 101 to be given broad construction. In particular, Fisher contends that § 101 requires only that the claimed invention "not be frivolous, or injurious to the well-being, good policy, or good morals of society," essentially adopting Justice Story's view of a useful invention from Lowell v. Lewis, 15 F. Cas. 1018, 1019 (No. 8568) (C.C. Mass. 1817). Under the correct application of the law, Fisher argues, the record shows that the claimed ESTs provide seven specific and substantial uses, regardless whether the functions of the genes corresponding to the claimed ESTs are known. Fisher claims that the Board's attempt to equate the claimed ESTs with the chemical compositions in Brenner was misplaced and that several decisions in the field of pharmaceuticals, namely, Cross v. Iizuka, 753 F.2d 1040 (Fed. Cir. 1985), Nelson v. Bowler, 626 F.2d 853 (C.C.P.A. 1980), and In re Jolles, 628 F.2d 1322 (C.C.P.A. 1980), are analogous and support finding utility of the claimed ESTs. Fisher likewise argues that the general commercial success of ESTs in the marketplace confirms the utility of the claimed ESTs. Hence, Fisher avers that the Board's decision was not supported by substantial evidence and should be reversed.

The government agrees with Fisher that the utility threshold is not high, but disagrees with Fisher's allegation that the Board applied a heightened utility standard. The government contends that a patent applicant need disclose only a single specific and substantial utility pursuant to Brenner, the very standard articulated in the PTO's "Utility Examination Guidelines" ("Utility Guidelines") and followed here when examining the '643 application. It argues that Fisher failed to meet that standard because Fisher's alleged uses are so general as to be meaningless. What is more, the government asserts that the same generic uses could apply not only to the five claimed ESTs but also to any EST derived from any organism. It thus argues that the seven utilities alleged by Fisher are merely starting points for further research, not the end point of any research effort. It further disputes the importance of the commercial success of ESTs in the marketplace, pointing out that Fisher's evidence involved only databases, clone sets, and microarrays, not the five claimed ESTs. Therefore, the government contends that we should affirm the Board's decision.

Several academic institutions and biotechnology and pharmaceutical companies[3] write as amici curiae in support of the government. Like the government, they assert that Fisher's claimed uses are nothing more than a "laundry list" of research plans, each general and speculative, none providing a specific and substantial benefit in currently available form. The amici also advocate that the claimed ESTs are the objects of further research aimed at identifying what genes of unknown function are expressed during anthesis and what proteins of unknown function are encoded for by those genes.

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[3] Amici in support of the government include Affymetrix, Inc., American College of Medical Genetics, Association of American Medical Colleges, Baxter Healthcare Corporation, Dow AgroSciences LLC, Eli Lilly and Company, Genentech, Inc., National Academy of Sciences, and the University of North Carolina School of Law.

Until the corresponding genes and proteins have a known function, the amici argue, the claimed ESTs lack utility under § 101 and are not patentable.

We agree with both the government and the amici that none of Fisher's seven asserted uses meets the utility requirement of § 101. Section 101 provides: "Whoever invents . . . any new and useful . . . composition of matter . . . may obtain a patent therefor . . . ." (Emphasis added). In Brenner, the Supreme Court explained what is required to establish the usefulness of a new invention, noting at the outset that "a simple, everyday word ["useful," as found in § 101] can be pregnant with ambiguity when applied to the facts of life." 383 U.S. at 529. Contrary to Fisher's argument that § 101 only requires an invention that is not "frivolous, injurious to the well-being, good policy, or good morals of society," the Supreme Court appeared to reject Justice Story's de minimis view of utility. Id. at 532-33 (citation omitted). The Supreme Court observed that Justice Story's definition "sheds little light on our subject," on the one hand framing the relevant inquiry as "whether the invention in question is 'frivolous and insignificant'" if narrowly read, while on the other hand "allowing the patenting of any invention not positively harmful to society" if more broadly read. Id. at 533. In its place, the Supreme Court announced a more rigorous test, stating:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Brenner, 383 U.S. at 534-35 (emphases added). Following Brenner, our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101. See, e.g., Fujikawa v.

Wattanasin, 93 F.3d 1559, 1563 (Fed. Cir. 1996) ("Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.").

The Supreme Court has not defined what the terms "specific" and "substantial" mean per se. Nevertheless, together with the Court of Customs and Patent Appeals, we have offered guidance as to the uses which would meet the utility standard of § 101. From this, we can discern the kind of disclosure an application must contain to establish a specific and substantial utility for the claimed invention.

Courts have used the labels "practical utility" and "real world" utility interchangeably in determining whether an invention offers a "substantial" utility. Indeed, the Court of Customs and Patent Appeals stated that "'[p]ractical utility' is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." Nelson, 626 F.2d at 856 (emphasis added).[4] It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.

Turning to the "specific" utility requirement, an application must disclose a use which is not so vague as to be meaningless. Indeed, one of our predecessor courts has observed "that the nebulous expressions 'biological activity' or 'biological properties'

[4] In Cross, this court considered the phrase "practical utility" to be synonymous with the phrase "substantial utility." 753 F.2d at 1047, n.13.

appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression 'useful for technical and pharmaceutical purposes' unsuccessfully relied upon by the appellant in In re Diedrich." In re Kirk, 376 F.2d 936, 941 (C.C.P.A. 1967). Thus, in addition to providing a "substantial" utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public.

In 2001, partially in response to questions about the patentability of ESTs, the PTO issued Utility Guidelines governing its internal practice for determining whether a claimed invention satisfies § 101. See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). The PTO incorporated these guidelines into the Manual of Patent Examining Procedure ("MPEP"). See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure § 2107 (8th ed. 2001, rev. May 2004). The MPEP and Guidelines "are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute." Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002) (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995)). According to the Utility Guidelines, a specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention. Manual of Patent Examining Procedure § 2107.01. The Utility Guidelines also explain that a substantial utility defines a "real world" use. In particular, "[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities." Id. Further, the Utility Guidelines discuss "research tools," a term often given to inventions used to conduct research. The PTO particularly cautions that

> [a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. [The PTO] must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.

Id. The PTO's standards for assessing whether a claimed invention has a specific and substantial utility comport with this court's interpretation of the utility requirement of § 101.

Turning to the parties' arguments, Fisher first raises a legal issue, charging that the Board applied a heightened standard for utility in the case of ESTs. Fisher apparently bases this argument on statements made by the Board in connection with its discussion of whether the claimed ESTs can be used to identify a polymorphism. In that context, the Board stated:

> Somewhere between having no knowledge (the present circumstances) and having complete knowledge of the gene and its role in the plant's development lies the line between 'utility' and 'substantial utility.' We need not draw the line or further define it in this case because the facts in this case represent the lowest end of the spectrum, i.e., an insubstantial use.

Board Decision, slip op. at 15 (emphasis added). Fisher reads the word "spectrum" out of context, claiming that the word somehow implies the application of a higher standard for utility than required by § 101. We conclude, however, that the Board did not apply an incorrect legal standard. In its decision, the Board made reference to a "spectrum" to differentiate between a substantial utility, which satisfies the utility requirement of § 101, and an insubstantial utility, which fails to satisfy § 101. The Board plainly did not announce or apply a new test for assessing the utility of ESTs. It simply followed the Utility Guidelines and MPEP, which mandate the specific and substantial utility test set forth in Brenner. Indeed, we note that Example 9 of the PTO's "Revised Interim Utility

Guidelines Training Materials" is applicable to the facts here. See U.S. Pat. & Trademark Off., Revised Interim Utility Guidelines Training Materials 50-53 (1999), available at www.uspto.gov/web/menu/utility.pdf. In that example, a cDNA fragment disclosed as being useful as a probe to obtain the full length gene corresponding to a cDNA fragment was deemed to lack a specific and substantial utility. Additionally, the MPEP particularly explains that a claim directed to a polynucleotide disclosed to be useful as a "gene probe" or "chromosome marker," as is the case here, fails to satisfy the specific utility requirement unless a specific DNA target is also disclosed. Manual of Patent Examining Procedure § 2107.01.

Regarding the seven uses asserted by Fisher, we observe that each claimed EST uniquely corresponds to the single gene from which it was transcribed ("underlying gene"). As of the filing date of the '643 application, Fisher admits that the underlying genes have no known functions. Fisher, nevertheless, claims that this fact is irrelevant because the seven asserted uses are not related to the functions of the underlying genes. We are not convinced by this contention. Essentially, the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. The overall goal of such experimentation is presumably to understand the maize genome – the functions of the underlying genes, the identity of the encoded proteins, the role those proteins play during anthesis, whether polymorphisms exist, the identity of promoters that trigger protein expression, whether protein expression may be controlled, etc. Accordingly, the claimed ESTs are, in words of the Supreme Court, mere "object[s] of use-testing," to wit, objects upon which scientific research could be

performed with no assurance that anything useful will be discovered in the end. Brenner, 383 U.S. at 535.

Fisher compares the claimed ESTs to certain other patentable research tools, such as a microscope. Although this comparison may, on first blush, be appealing in that both a microscope and one of the claimed ESTs can be used to generate scientific data about a sample having unknown properties, Fisher's analogy is flawed. As the government points out, a microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. One of the claimed ESTs, by contrast, can only be used to detect the presence of genetic material having the same structure as the EST itself. It is unable to provide any information about the overall structure let alone the function of the underlying gene. Accordingly, while a microscope can offer an immediate, real world benefit in a variety of applications, the same cannot be said for the claimed ESTs. Fisher's proposed analogy is thus inapt. Hence, we conclude that Fisher's asserted uses are insufficient to meet the standard for a "substantial" utility under § 101.

Moreover, all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world. Focusing on the two uses emphasized by Fisher at oral argument, Fisher maintains that the claimed ESTs could be used to identify polymorphisms or to isolate promoters. Nevertheless, in the face of a utility rejection, Fisher has not presented any evidence, as the Board well noted, showing that the claimed ESTs have been used in either way. That is, Fisher does not present either a single polymorphism or a single promoter,

assuming at least one of each exists, actually identified by using the claimed ESTs. Further, Fisher has not shown that a polymorphism or promoter so identified would have a "specific and substantial" use. The Board, in fact, correctly recognized this very deficiency and cited it as one of the reasons for upholding the examiner's final rejection.

With respect to the remaining asserted uses, there is no disclosure in the specification showing that any of the claimed ESTs were used as a molecular marker on a map of the maize genome. There also is no disclosure establishing that any of the claimed ESTs were used or, for that matter, could be used to control or provide information about gene expression. Significantly, despite the fact that maize leaves produce over two thousand different proteins during anthesis, Fisher failed to show that one of the claimed ESTs translates into a portion of one of those proteins. Fisher likewise did not provide any evidence showing that the claimed ESTs were used to locate genetic molecules in other plants and organisms. What is more, Fisher has not proffered any evidence showing that any such generic molecules would themselves have a specific and substantial utility. Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a "substantial" utility under § 101.

Furthermore, Fisher's seven asserted uses are plainly not "specific." Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. That is, any EST transcribed from any gene in the maize genome may be a molecular marker or a source for primers. Likewise, any EST transcribed from any gene in the maize genome may be used to measure the level of mRNA in a

tissue sample, identify the presence or absence of a polymorphism, isolate promoters, control protein expression, or locate genetic molecules of other plants and organisms. Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

We agree with the Board that the facts here are similar to those in Brenner. There, as noted above, the applicant claimed a process for preparing compounds of unknown use. Similarly, Fisher filed an application claiming five particular ESTs which are capable of hybridizing with underlying genes of unknown function found in the maize genome. The Brenner court held that the claimed process lacked a utility because it could be used only to produce a compound of unknown use. The Brenner court stated: "We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product." 383 U.S. at 535. Applying that same logic here, we conclude that the claimed ESTs, which do not correlate to an underlying gene of known function, fail to meet the standard for utility intended by Congress.

In addition to approving of the Board's reliance on Brenner, we observe that the facts here are even more analogous to those presented in Kirk, 376 F.2d 936, and In re Joly, 376 F.2d 906 (C.C.P.A. 1967), two cases decided by our predecessor court shortly after Brenner. In Kirk, the applicant sought to patent new steroidal compounds

disclosed as having two possible utilities. First, the applicant alleged that the claimed compounds were useful for their "biological activity" because "one skilled in the art would know how to use the compounds . . . to take advantage of their presently-existing biological activity." Kirk, 376 F.2d at 939. The court rejected this claimed utility on the ground that it was not sufficiently "specific," but was instead "nebulous." Id. at 941.

Second, the applicant asserted that the claimed compounds could be used by skilled chemists as intermediates in the preparation of final steroidal compounds of unknown use. Relying on Brenner, the court reasoned:

> It seems clear that, if a process for producing a product of only conjectural use is not itself "useful" within § 101, it cannot be said that the starting materials for such a process – i.e., the presently claimed intermediates – are "useful." It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use. Cf. Reiners v. Mehltretter, 236 F.2d 418, 421 [(C.C.P.A. 1956)] where compounds employed as intermediates to produce other directly useful compounds were found to be themselves useful.

Id. at 945-46 (emphasis added). Therefore, the court affirmed the Board's rejection of the claimed compounds for lack of utility.

The facts in Joly are nearly identical to the facts in Kirk. The Joly applicant filed an application claiming compounds useful as intermediates in preparing steroids that were themselves not shown or known to be useful, but that were similar in chemical structure to steroids of known pharmacological usefulness. The court adopted the reasoning of the Kirk court in its entirety and affirmed the Board's decision rejecting the claimed intermediates for failing to comply with § 101. Joly, 376 F.2d at 908-09.

Just as the claimed compounds in Kirk and Joly were useful only as intermediates in the synthesis of other compounds of unknown use, the claimed ESTs can only be used as research intermediates in the identification of underlying protein-encoding genes of unknown function. The rationale of Kirk and Joly thus applies here. In the words of the Kirk court:

> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

376 F.2d at 942 (emphasis added).

That the Kirk and Joly decisions involved chemical compounds, while the present case involves biological entities, does not distinguish these decisions. The rationale presented therein, having been drawn from principles set forth by the Supreme Court in Brenner, applies with equal force in the fields of chemistry and biology as well as in any scientific discipline. In Brenner, the Supreme Court was primarily concerned with creating an unwarranted monopoly to the detriment of the public:

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. . . . This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now

> seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy.

Brenner, 383 U.S. at 535-36 (citations, quotation, and footnote omitted). Here, granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher's claimed ESTs may add a noteworthy contribution to biotechnology research, our precedent dictates that the '643 application does not meet the utility requirement of § 101 because Fisher does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

2.

Fisher's reliance on Jolles, Nelson, and Cross, cases which found utility in certain claimed pharmaceutical compounds, is misplaced. In Jolles, the applicant filed an application claiming naphthacene compounds useful in treating acute myloblastic leukemia. To support the asserted utility, the applicant presented in vivo data showing eight of the claimed compounds effectively treated tumors in a mouse model. Our predecessor court reversed the Board's affirmance of the final rejection for lack of utility, finding that the structural similarity between the compounds tested in vivo and the

remaining claimed compounds was sufficient to establish utility for the remaining claimed compounds. Jolles, 628 F.2d at 1327-28.

In Nelson, decided by the Court of Customs and Patent Appeals in the same year as Jolles, Nelson claimed prostaglandin compounds. The PTO declared an interference with an application filed by Bowler claiming the same compounds. The issue before the Board was whether Nelson had established utility for the claimed prostaglandins as smooth muscle stimulants and blood pressure modulators via in vivo and in vitro data, specifically, an in vivo rat blood pressure test and an in vitro gerbil colon smooth muscle stimulation test. The Board declined to award priority to Nelson, characterizing Nelson's tests as "rough screens, uncorrelated with actual utility [in humans]." Our predecessor court reversed, concluding that "tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use." Nelson, 626 F.2d at 856.

In Cross, decided by the Federal Circuit five years after Jolles and Nelson, Iizuka filed an application claiming thromboxane synthetase inhibitors, alleged to be useful in treating inflammation, asthma, hypertension, and other ailments. When Cross filed an application claiming the same compounds two months after Iizuka, the PTO declared an interference. The dispositive issue concerned whether Iizuka's Japanese priority application disclosed utility for the claimed inhibitors. The Board concluded that it offered a sufficient disclosure based upon in vitro data showing strong inhibitory action for thromboxane synthetase for structurally-similar compounds in human or bovine platelet microsomes. We affirmed, reasoning:

> Opinions of our predecessor court have recognized the fact that pharmacological testing of animals is a screening procedure for testing

> new drugs for practical utility. This in vivo testing is but an intermediate link in a screening chain which may eventually lead to the use of the drug as a therapeutic agent in humans. We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question. Successful in vitro testing will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an in vivo utility.

Cross, 753 F.2d at 1050 (citations omitted).

The facts in these three cases are readily distinguishable from the facts here. In Jolles, Nelson, and Cross, the applicants disclosed specific pharmaceutical uses in humans for the claimed compounds and supported those uses with specific animal test data, in vitro, in vivo, or both. In contrast, Fisher disclosed a variety of asserted uses for the claimed ESTs, but failed to present any evidence – test data, declaration, deposition testimony, or otherwise – to support those uses as presently beneficial and hence practical. Fisher did not show that even one of the claimed ESTs had been tested and successfully aided in identifying a polymorphism in the maize genome or in isolating a single promoter that could give clues about protein expression. Adopting the language of the Cross court, the alleged uses in Jolles, Nelson, and Cross were not "nebulous expressions, such as 'biological activity' or 'biological properties' [alleged in the application in Kirk]," that "convey little explicit indication regarding the utility of a compound." Cross, 753 F.2d at 1048. Instead, the alleged uses in those cases gave a firm indication of the precise uses to which the claimed compounds could be put. For example, in Nelson, the claimed prostaglandins could be used to stimulate smooth muscle or modulate blood pressure in humans as shown by both in vivo and in vitro animal data. Hence, the Jolles, Nelson, and Cross courts concluded that the claimed

pharmaceutical compounds satisfied the specific and substantial utility requirements of § 101. We cannot reach that same conclusion here. Fisher's laundry list of uses, like the terms "biological activity" or "biological properties" alleged in Kirk, are nebulous, especially in the absence of any data demonstrating that the claimed ESTs were actually put to the alleged uses.

Fisher's reliance on the commercial success of general EST databases is also misplaced because such general reliance does not relate to the ESTs at issue in this case. Fisher did not present any evidence showing that agricultural companies have purchased or even expressed any interest in the claimed ESTs. And, it is entirely unclear from the record whether such business entities ever will. Accordingly, while commercial success may support the utility of an invention, it does not do so in this case. See Raytheon Co. v. Roper Corp., 724 F.2d 951, 959 (Fed. Cir. 1983) (stating that proof of a utility may be supported when a claimed invention meets with commercial success).

3.

As a final matter, we observe that the government and its amici express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the "useful Arts" and "Science." See U.S. Const. art. I, § 8, cl. 8. The government and its amici point out that allowing EST claims like Fisher's would give rise to multiple patents, likely owned by several different companies, relating to the same underlying gene and expressed protein. Such a situation, the government and amici predict, would result in an unnecessarily convoluted licensing environment for those interested in researching that gene and/or protein.

The concerns of the government and amici, which may or may not be valid, are not ones that should be considered in deciding whether the application for the claimed ESTs meets the utility requirement of § 101. The same may be said for the resource and managerial problems that the PTO potentially would face if applicants present the PTO with an onslaught of patent applications directed to particular ESTs. Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. They are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law. Under Title 35, an applicant is entitled to a patent if his invention is new, useful, nonobvious, and his application adequately describes the claimed invention, teaches others how to make and use the claimed invention, and discloses the best mode for practicing the claimed invention. What is more, when Congress enacted § 101, it indicated that "anything under the sun that is made by man" constitutes potential subject matter for a patent. S. Rep. No. 82-1979, at 7 (1985). Policy reasons aside, because we conclude that the utility requirement of § 101 is not met, we hold that Fisher is not entitled to a patent for the five claimed ESTs.

B. Enablement

Fisher asserts that we should reverse the enablement rejection upheld by the Board since the Board made it contingent upon the utility rejection, which Fisher argues was not supported by substantial evidence for reasons analyzed above. The government argues to the contrary, asserting that claim 1 of the '643 application cannot

be enabled because the claimed ESTs were not disclosed as having a specific and substantial utility. We agree with the government. It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101.

> The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.

Ziegler, 992 F.2d at 1200-01 (citations omitted); see also Kirk, 376 F.2d at 942 ("Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention."); In re Brana, 51 F.3d 1560, 1564 (Fed. Cir. 1995) ("Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it."); Manual of Patent Examining Procedure § 2107.01. Here, in light of our conclusion that the Board's decision with respect to utility applied the correct legal standard and was supported by substantial evidence, we conclude that Fisher failed to satisfy the enablement requirement. Consequently, we leave undisturbed the enablement rejection of the '643 application under § 112, first paragraph.

III. CONCLUSION

We conclude that substantial evidence supports the Board's findings that each of the five claimed ESTs lacksa specific and substantial utility and that they are not enabled. Accordingly, the Board's decision affirming the final rejection of claim 1 of the '643 patent for lack of utility under § 101 and lack of enablement under § 112, first paragraph, is affirmed.

AFFIRMED

United States Court of Appeals for the Federal Circuit

04-1465
(Serial No. 09/619,643)

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI

RADER, Circuit Judge, dissenting.

This court today determines that expressed sequence tags (ESTs) do not satisfy 35 U.S.C. § 101 unless there is a known use for the genes from which each EST is transcribed. While I agree that an invention must demonstrate utility to satisfy § 101, these claimed ESTs have such a utility, at least as research tools in isolating and studying other molecules. Therefore, I respectfully dissent.

Several, if not all, of Fisher's asserted utilities claim that ESTs function to study other molecules. In simple terms, ESTs are research tools. Admittedly ESTs have use only in a research setting. However, the value and utility of research tools generally is beyond question, even though limited to a laboratory setting. See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure (MPEP) § 2107.01 at 2100-33 (8th ed. 2001, rev. Feb. 2003) ("Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds)."). Thus, if the claimed ESTs qualify as research tools, then they have a "specific" and "substantial" utility sufficient for § 101. If these ESTs do not enhance research, then Brenner v. Manson, 383 U.S. 519 (1966) (involving the patentability of methods for producing compounds having no known use) controls and erects a § 101 bar for lack of utility. For

the following reasons, these claimed ESTs are more akin to patentable research tools than to the unpatentable methods in Brenner.

In Brenner, the Court confronted a growing conflict between this court's predecessor, the Court of Customs and Patent Appeals (CCPA), and the Patent Office over the patentability of methods of producing compounds with no known use. This conflict began with In re Nelson, 280 F.2d 172 (CCPA 1960), the first in a series of cases wherein the CCPA reversed several Patent Office utility rejections. Brenner, 383 U.S. at 530. Brenner put an end to these cases because, in the 1960s, the Court could not distinguish between denying patents to compounds with no known use and denying patents to methods of producing those useless compounds. The Court commented:

> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.

Id. at 535. This court's predecessor later extended Brenner to bar patents on compounds as intermediates in the preparation of other compounds having no known use. See In re Kirk, 376 F.2d 936 (CCPA 1967) (rejecting intermediaries for steroids with no known use). These cases, however, share a common underpinning - a method of producing a compound with no known use has no more benefit to society than the useless compound itself.

This case is very different. Unlike the methods and compounds in Brenner and Kirk, Fisher's claimed EST's *are* beneficial to society. As an example, these research tools "may help scientists to isolate the particular underlying protein-encoding genes . . . [with the] overall goal of such experimentation . . . presumably [being] to understand the

maize genome[.]" Majority Opinion, slip op. at 13. They also can serve as a probe introduced into a sample tissue to confirm "that the gene corresponding to the EST was being expressed in the sample tissue at the time of mRNA extraction." Id., slip op. at 3.

These research tools are similar to a microscope; both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure. Both supply information about a molecular structure. Both advance research and bring scientists closer to unlocking the secrets of the corn genome to provide better food production for the hungry world. If a microscope has § 101 utility, so too do these ESTs.

The Board and this court acknowledge that the ESTs perform a function, that they have a utility, but proceed quickly to a value judgment that the utility would not produce enough valuable information. The Board instead complains that the information these ESTs supply is too "insubstantial" to merit protection. Yet this conclusion denies the very nature of scientific advance. Science always advances in small incremental steps. While acknowledging the patentability of research tools generally (and microscopes as one example thereof), this court concludes with little scientific foundation that these ESTs do not qualify as research tools because they do not "offer an immediate, real world benefit" because further research is required to understand the underlying gene. This court further faults the EST research for lacking any "assurance that anything useful will be discovered in the end." These criticisms would foreclose much scientific research and many vital research tools. Often scientists embark on research with no assurance of success and knowing that even success will demand "significant additional research."

Nonetheless, this court, oblivious to the challenges of complex research, discounts these ESTs because it concludes (without scientific evidence) that they do not supply enough information. This court reasons that a research tool has a "specific" and "substantial" utility *only* if the studied object is readily understandable using the claimed tool - that no further research is required. Surely this cannot be the law. Otherwise, only the final step of a lengthy incremental research inquiry gets protection.

Even with a microscope, significant additional research is often required to ascertain the particular function of a "revealed" structure. To illustrate, a cancerous growth, magnified with a patented microscope, can be identified and distinguished from other healthy cells by a properly trained doctor or researcher. But even today, the scientific community still does not fully grasp the reasons that cancerous growths increase in mass and spread throughout the body,[1] or the nature of compounds that interact with them, or the interactions of environmental or genetic conditions that contribute to developing cancer. Significant additional research is required to answer these questions. Even with answers to these questions, the cure for cancer will remain in the distance. Yet the microscope still has "utility" under § 101. Why? Because it takes the researcher one step closer to answering these questions. Each step, even if

[1] ESTs have already been used to advance cancer research well beyond what is achievable using microscopes alone. See Andy J. Minn, Genes That Mediate Breast Cancer Metastisis To Lung, Nature, July 28, 2005 at 518-24 (discussing research to identify genes that mark and mediate breast cancer metastisis to the lung).

small in isolation, is nonetheless a benefit to society sufficient to give a viable research tool "utility" under § 101. In fact, experiments that fail still serve to eliminate some possibilities and provide information to the research process.

The United States Patent Office, above all, should recognize the incremental nature of scientific endeavor. Yet, in the interest of easing its administrative load, the Patent Office will eliminate some research tools as providing "insubstantial" advances. How does the Patent Office know which "insubstantial" research step will contribute to a substantial breakthrough in genomic study? Quite simply, it does not.

In addition, this court faults Fisher for not presenting evidence of utility showing that the claimed ESTs "have been used in the real world." To the contrary, this court misapprehended the proper procedure. Fisher asserted seven different utilities. The Board rejected two of these assertions outright as "insubstantial." See Ex parte Fisher, App. No. 2002-2046, slip. op at 14-16 (Bd. Pat. App. and Int. 2004) (acknowledging that the ESTs may be able to detect "the absence of a polymorphism" and "to isolate nucleic acid molecules of other plants and organisms[,]" but finding such utilities are not "substantial" even if the ESTs can perform them). This summary dismissal deprived Fisher of any chance to proffer evidence. Rather than fault Fisher for not presenting evidence it was prevented from offering, this court should instead observe that the Board did not satisfy its burden of challenging Fisher's presumptively correct assertion that the ESTs were *capable* of performing those functions. See MPEP § 2107.02(IV) at 2100-40 (noting that the initial burden is on the office to establish a prima facie case as to lack of utility and to provide evidentiary support thereof); In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (where an applicant has asserted utility in the disclosure, the

Patent Office has the initial burden of challenging this presumptively correct assertion of utility).

Abandoning the proper legal procedure, the Board reasoned that the molecules studied with these ESTs showed no particular use, therefore the ESTs themselves also lacked a utility. In so ruling, the Board did not reject Fisher's utilities on the basis that the ESTs were *unable to perform* the purported utilities. Thus, the Board did not establish a prima facie challenge to the ESTs' ability to perform these two utilities. Without anything to rebut, Fisher had no obligation or opportunity to provide evidence in rebuttal. Thus, I respectfully disagree with this court's conclusion that the Board's decision can be affirmed on the basis that Fisher did not supply evidence of the ESTs' ability to perform the asserted utilities.

In truth, I have some sympathy with the Patent Office's dilemma. The Office needs some tool to reject inventions that may advance the "useful arts" but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing "insubstantially" to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions. See In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995); Martin J. Adelman et al., Patent Law, 517 (West Group 1998) (commenting that scholars have been critical of Deuel, which "overly favored patent applicants in biotech by adopting an

overly lax nonobviousness standard." (citing Anita Varma & David Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J. L. & Tech. 53 (1996))); Philippe Ducor, The Federal Circuit and In re Deuel: Does §103 apply to Naturally Occurring DNA?, 77 J. Pat. & Trademark Off. Soc'y 871, 883 (Nov. 1995) ("The Court of Appeals for the Federal Circuit could have formulated its opinion in only one sentence: '35 U.S.C. § 103 does not apply to newly retrieved natural DNA sequences.'"); Philippe Ducor, Recombinant Products and Nonobviousness: A Typology, 13 Santa Clara Computer and High Tech. L.J. 1, 44-45 (Feb. 1997) ("This amounts to a practical elimination of the requirement for nonobviousness for these products, even when all the information necessary to discover them is previously available."); see also over fifty additional articles critical of Deuel in the "Citing References" tab for Deuel on Westlaw. Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used world wide for such assessments (other than in the United States), namely inventive step or obviousness.

Thus, for the foregoing reasons, I would find that Fisher's asserted utilities qualify the claimed ESTs as research tools useful in the study of other molecules. Because research tools provide a cognizable benefit to society, much like a microscope, the ESTs claimed here have "utility" under § 101. In addition, the enablement rejection should also be reversed because it was a consequence of the finding of lack of utility.